REMARKS

Claims 1-4, 6-19 and 21-26 are presently pending. Claims 14-19 and 21-23 have been withdrawn from consideration, however, Applicants note that the claims are dependent on the claims under active consideration, so that they should also be allowed upon the allowance of the claims from which they depend. Claims 1, 9, 12, and 24-26 are amended herein. The amendments to the claims are fully supported by the specification and original claims. No new matter has been added. Specifically, claims 1, 9, 24 and 25, have been amended to more clearly set forth the fact that removal of GMP from the lactic raw material is accomplished by adsorbing the GMP onto the anionic resin. This amendment is supported by the specification, for example, at page 5, lines 3-5 (". . . recovering the GMP **adsorbed** onto the resin by elution."), also see Examples 1-5, and at page 7, lines 7-19. The amendments to Claim 12 were also made for clarification purposes. The use of the terms "rinse" and "wash" instead of just "washings" was made to avoid confusion that may have been caused. These amendments are supported by the specification at, for example, page 7, lines 7-19 (". . .washing the resin . . . to obtain an eluate" and page 9, lines 27-31 (". . . rinsed with 30 L of deionized water").

Claims 1-4, 6-13, and 24-26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for the reasons set forth on pages 2-3 of the Office Action.

Claim 1 was rejected for the use of the term "fraction." The term "fraction" was added to the claims at the suggestion of the Examiner during the Interview held on November 4, 2002. While a GMP enriched "fraction" does mean that more than just "GMP" could be present, it does not make the present claim indefinite. While it is preferable and generally true that the GMP enriched fraction obtained by Applicants' process contains less than 1% by weight of fat, less than 0.2% by weight of lactose, and less than 3% by weight of true whey products, such a limitation would be overly narrowing and would deny the Applicants the proper scope of protection warranted by their invention of a commercially viable process of separating GMP from lactic raw material in a single operation, on an industrial scale with high yields.

Claim 8 was rejected for the use of "about." Applicants respectfully disagree with that the use of the term "about" makes claim 8 indefinite. The term "about" is fully supported by the specification, for example, at page 6, lines 11-12, and is a commonly used term in many issued patents, for example, a simple search of the USPTO patent database for issued patents using the term "about" in the claim language resulted in 680,893 hits. The term "about" as used in claim 8, does not render the claim indefinite to one skilled in the art,

but simply signifies to one skilled in the art that the exact pH is not critical to the successful use of this step of the inventive process.

Claim 12 was rejected for lack of antecendent basis for the phrases "the eluate" and "the washings." Claim 12 has now been amended to properly address the antecendent basis.

Claim 12 was also rejected as requiring that the GMP be "desorbed," with no requirement that the GMP be adsorbed. Claim 1 has now been amended to replace the term "remove" GMP with the term "adsorb" GMP, this rejection is now moot.

Claim 26 was rejected as being duplicative of claim 25. Claim 26 has been amended to clarify that the narrowing element of claim 26 requires that the composition be an antithrombotic pharmaceutical composition with GMP as the antithrombotic agent.

In view of the above, Applicants respectfully request the Examiner withdraw the rejection under 35 U.S.C. §112, second paragraph.

Claims 1-4, 8-13, and 24-25 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,434,250 to Shimatani for the reasons set forth on pages 5-7 of the action. Applicants traverse.

Applicants note that Claims 6 and 7 are free from the prior art as they require the GMP to be adsorbed onto the resin, which the prior art does not teach. Independent claims 1, 9, 24 and 25 have now been amended to substitute the term "remove" GMP with the term "adsorb" GMP onto the anionic resin. This amendment was made to clarify that Applicants' process "removes" GMP from the deionized lactic raw material by **"adsorbing" the GMP onto the anionic resin** and not by some other means.

In contrast, Shimatani discloses and claims a process for obtaining sialic acids by contacting whey with a cation exchanger to produce **an exhanger-passed solution**. The exchanger passed solution is high in α-La and is further concentrated by using ultratfiltration **"in order to efficiently remove GMP from the exchanger-passed solution** and to enhance the α-La content." *See* Shimatani at Col. 3, line 68 to Col. 4, line 2. Shimatani does not teach or suggest the Applicants' invention, especially not, the step of contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to **adsorb GMP onto the anionic resin** from the substantially deionized lactic raw material. There is no motivation in Shimatani to develop Applicants' presently claim invention either, as the intent of teachings of Shimatani is to enhance the α-La content and to rid the composition of GMP through ultrafiltration. The dissimilar purposes of Shimatani's process and Applicants' process are

evidenced in the divergent steps required by each process and the different end products produced by each. Without at least some suggestion of this step of **adsorbing the GMP onto the anionic resin**, Shimatani cannot make obvious Applicants invention.

Furthermore, the steps of separating the adsorbed GMP enriched fraction from the resin is also not taught or suggested by Shimatani. As Shimatani does not teach Applicants' presently claimed process of adsorbing the GMP onto the anionic resin there would be no need to separate the adsorbed GMP from the resin as the resin never adsorbed it in the first place. Shimatani teaches different techniques, such as ultrafiltration and lowering the pH, to try to remove the GMP from the **exchanger-passed solution** to enhance the α-La content. *See* Shimatani at Col 2, lines 25-30 and Col. 3, line 68 to Col. 4, line 2.

The limitations set forth in the claims cannot be set aside in order to determine obviousness. As pointed out above, the limitations of Applicants' presently claimed invention are not taught or suggested by Shimantani and therefore cannot make them obvious.

Like claims 6 and 7, claims 1-4, 8-13, and 24-26 should also be free of the prior art. Applicants' respectfully request that the obviousness rejection be withdrawn in view of these facts.

The Examiner further rejects, Claims 1-4, 8-13 and 24-25 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,434,250 to Shimatani in view of Marshall (Ref. AL), for the reasons set forth on pages 9-10. Applicants traverse this rejection.

As discussed above, Shimatani fails to teach or suggest the steps of Applicants' process, specifically the steps of **adsorbing GMP onto the anionic resin** from the substantially deionized lactic raw material and **separating the adsorbed GMP** from the anionic resin. Marshall fails to remedy the deficiencies of Shimatani. Marshall does teach the fact that GMP is a useful peptide, but fails to teach or suggest a method of obtaining GMP. Due to the fact that neither Shimatani nor Marshall suggest alone or in combination the steps of Applications' process, this rejection should also be withdrawn.

The Examiner further rejects, Claims 1-4, 8-13, and 24-25 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,278,288 to Kawasaki, for the reasons set forth on page 9-10. Applicants' traverse.

Kawasaki is directed to a process of producing κ-casein glycomacropeptides. The process of Kawasaki involves the steps of contacting milk raw materials containing the 1/2 casein glycomacropeptide with a **cation exchanger** and collecting a fraction which does not adsorb on the cation exchanger to obtain the κ-casein glycomacropeptides. *See* Kawaski at Col. 8, lines 1-11 and Abstract. The process of Kawasaki specifically teaches and requires

that the fraction **not adsorbed** on the ion exchanger (the filtrate) should be collected as it contains the $_K$-casein glycomacropeptides.

In contrast, Applicants' process, as explained in more detail above, requires the substantially deionized lactic raw material to be contacted with **an anionic resin having a hydrophobic matrix to adsorb GMP onto the anionic resin.** In Applicants' process the GMP enriched fraction **is adsorbed** on the anionic resin. Once the GMP is adsorbed on the anionic resin, the filtrate and the resin (GMP bound) is separated, followed by the separation of the **adsorbed** GMP enriched fraction from the resin. In Applicants' presently claimed process, the anionic resin acts to remove GMP from the lactic raw material. Furthermore, with no teaching or suggestion of this step of Applicants' invention, the step of **separating the adsorbed GMP** from the resin is also not taught or suggested by Kawasaki.

For these reasons, Kawasaki cannot make obvious Applicants' invention and this rejection should also be withdrawn.

The Examiner further rejects claims 25-26 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,434,250 to Shimatani in view of U.S. Patent No. 5,063,203 to Drouet or in the alternative over U.S. Patent No. 5,278,288 to Kawasaki in view of U.S. Patent No. 5,063,203 to Drouet for the reasons set forth on pages 9-11.

As explained above in detail, neither Kawasaki nor Shimatani teach or suggest Applicants' presently claimed process. The references fail to teach the steps of Applicants' presently claimed process, in particular the step of contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix **to adsorb GMP onto the anionic resin** from the lactic raw material.

Drouet does nothing to remedy the deficiencies of Kawasaki and Shimatani. Drouet simply discloses that GMP inhibits thrombosis, but does not disclose any process of obtaining GMP.

Therefore, Applicants respectfully request that the 35 U.S.C. §103(a) rejection be withdrawn.

In view the foregoing remarks and amendments it is believed that the entire application is now in condition for allowance. Should any issues remain please call Allan Fanucci at (212) 294-3311 or Rodney Fuller at (202) 371-5838 in order to expedite the allowance of all the claims in this application.

Respectfully submitted,

Date: 7/17/03

Rodney J. Fuller (Reg. No. 46,714)
For: Allan A. Fanucci (Reg. No. 30,256)

WINSTON & STRAWN
Customer No. 28765

(202) 371-5838